US ERA ARCHIVE DOCUMENT

Reviewer: Eugenia McAndrew

**Product Manager: 22** 

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STUDY TYPE: Acute Oral Toxicity - S-D Rat; OPPTS 870.1100; OECD 401

TEST MATERIAL: Chlorothalonil Technical (Lot # 218/87; 98.63 % purity; white powder)

<u>CITATION</u>: Cummins, H.A. Chlorothalonil Technical: Acute Oral Toxicity Study in the Rat. Life Science Research Rome Toxicology Centre S.P.A., Rome, Italy. Laboratory Report Number 88/CFA002/276. March 29, 1988. MRID 45710203. Unpublished.

**SPONSOR:** Chlorothalonil Technical (Lot # 218/87; 98.63 % purity; white powder)

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45710203), five/sex CD young adult albino rats (Source: Charles River (UK) Limited, Margate, Kent, England, PA; 99-110 g males and 88-101 g females) were given a single oral dose of Chlorothalonil Technical (Lot # 218/87; 98.63 % purity; white powder) at 5000 mg/kg. The test article was prepared as a suspension in 0.5% w/v methylcellulose in distilled water to make dosing by gavage possible. Animals were then observed for 14 days.

Oral LD<sub>50</sub> Males => 5000 mg/kg Oral LD<sub>50</sub> Females => 5000 mg/kg Oral LD<sub>50</sub> Combined => 5000 mg/kg

One male rat was killed *in extremis* in day 5. Toxic signs noted prior to death included decreased motor activity, piloerection, breathing irregularities, abdominal bloat, hunched posture, hairloss and thin body conformation. The other nine animals survived and gained weight. Clinical signs noted included decreased motor activity and piloerection for the first five hours after dosing. The animals recovered from these symptoms by day 2. Necropsy of the decedent revealed distention of the gastro-intestinal tract and kidney pallor. Necropsy of the rats at study termination on day 15 revealed no significant lesions.

Toxicity based on one death at the limit dose. EPA Toxicity Category IV.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 401) in the rat.

**COMPLIANCE**: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## **RESULTS and DISCUSSION:**

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	1/5	0/5	1/10

- A. Mortality One male rat was killed in extremis in day 5.
- **B.** <u>Clinical observations</u> One male rat was killed *in extremis* in day 5. Toxic signs noted prior to death included decreased motor activity, piloerection, breathing irregularities, abdominal bloat, hunched posture, hairloss and thin body conformation. The other nine animals survived and gained weight. Clinical signs noted included decreased motor activity and piloerection for the first five hours after dosing. The animals recovered from these symptoms by day 2.
- C. <u>Gross Necropsy</u> -Necropsy of the decedent revealed distention of the gastro-intestinal tract and kidney pallor. Necropsy of the rats at study termination on day 15 revealed no significant lesions.
- D. Reviewer's Conclusions: Agree with the study author